IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Seroquel XR (Extended Release Quetiapine Fumarate) Antitrust Litigation	Master Docket No. 20-1076-CFC
This Document Relates to:	
All Actions	

MEMORANDUM ORDER

Defendants have moved pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) to preclude Plaintiffs' expert Susan Marchetti from offering at trial her financial incentive and capacity opinions. D.I. 646.

I.

Federal Rule of Evidence 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and

> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702. In *Daubert*, the Supreme Court held that district courts must act as gatekeepers to ensure that proffered expert scientific testimony meets the requirements of Rule 702. *See* 509 U.S. at 589. And in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), the Court held that "this basic gatekeeping obligation" "applies to all expert testimony," and not just "scientific" testimony. *Id.* at 147.

II.

The thrust of Ms. Marchetti's financial incentive opinion is set forth in paragraph 46 of her Opening Report. It reads:

> [I]n the absence of its agreement with Handa not to launch an AG in competition with Handa during Handa's 180-day exclusivity period, AstraZeneca or a rational pharmaceutical company in AstraZeneca's position would have had, and recognized, strong financial incentives to launch an AG between May 2015 and November 2016 when generic Seroquel XR first launched.

D.I. 707-1 ¶ 46.

Defendants seek to exclude Ms. Marchetti's financial incentive opinion under Rule 702(c) and (d), arguing that her opinion is not the product of reliable methods and principles and does not reflect a reliable application of such methods and principles to the facts of the case. D.I. 647 at 3. The crux of Defendants' argument in favor of exclusion is this: Ms. Marchetti "cannot purport to give an

opinion on AstraZeneca's 'financial incentives,'" given she did not consider "*any* other competition strategy" AstraZeneca could have taken in lieu of launching an AG, such as a rebating strategy. D.I. 774 at 3, 6 (emphasis in the original).

I will not exclude Ms. Marchetti's financial incentive opinion on this basis. "[A]n expert's failure to consider every available fact or option neither renders [her] methodology unreliable" nor her application of that methodology to the facts of the case unreliable "but, rather, goes to the weight of [her] testimony." *Sikkelee v. Precision Airmotive Corp.*, 522 F. Supp. 3d 120, 156 (M.D. Pa. 2021) (internal quotation marks and citation omitted). "Defendants' critiques of Marchetti's opinion are appropriately reserved for cross-examination." *In re Zetia (Ezetimibe) Antitrust Litig.*, 655 F. Supp. 3d 406, 434 (E.D. Va. 2023). They do not, however, warrant exclusion.

III.

Ms. Marchetti's capacity opinion is set forth in paragraphs 56 through 63 of the report. Those paragraphs read:

> 56. AstraZeneca is a global company with a large network that includes 28 manufacturing facilities in 16 countries. Two of those facilities, Newark, Delaware and Macclesfield, UK are among the largest in the AZ network and the evidence shows that both facilities were capable of and did manufacture Seroquel XR. A December 2020 interview with AstraZeneca Plant Engineer John Myers states that "The primary function [of the Newark site] is end-to-end production. A large proportion of AstraZeneca's products are manufactured, formulated,

packed, warehoused, tested, and distributed from this location . . . . Upwards of 50 percent of . . . U.S. sales are distributed from the Newark facility." Another AstraZeneca website describes Macclesfield as "the biggest pharmaceutical manufacturing site in the UK, the base for our second largest global IT hub and the home of Pharmaceutical Technology, Global Quality and Supply Chain & Strategy teams."

57. Global manufacturing companies such as AstraZeneca and Pfizer often have several facilities that have similar manufacturing and technology capabilities. It was my responsibility at Pfizer to review the total U.S. supply pipeline annually and determine which facility or facilities were best suited to manufacture certain products for the U.S. market. Considerations included balancing capacity, (both equipment and labor), optimizing manufacturing and distribution costs, and consideration of possible changes in market demand, including an authorized generic launch.

58. The Newark manufacturing facility made products not only for the U.S. but also for non-US or "ROW" (rest of world) markets. In his deposition, Brian Dell confirmed that AstraZeneca could free capacity for Seroquel XR Authorized Generic production by transferring production of non-US Seroquel XR to Macclesfield. Many U.S. Pfizer facilities made product for non-US or "ROW" markets as well. If faced with a capacity constraint for the U.S. market, I would also look at opportunities to transfer ROW products to alternative manufacturing sites. Although managing a complex supply chain for companies like AstraZeneca and Pfizer can be challenging, the flexibility that these large organizations offer in terms of both technology and resources provides multiple options for managing change. In a memo dated March 9, 2011, from Kathy Sailor to Michael Crawford and Tanya Harris titled "Seroquel XR AG Meeting," Ms. Sailer considered contingencies for supplying a Seroquel XR authorized generic in late 2011, including "ask[ing]

Macclesfield to take back production of XR 300mg. This would take 2 - 3 batches per week out of the [Newark granulation] schedule…". This memo demonstrates that AstraZeneca considered using its supply chain network to balance capacity loading. This type of analysis is consistent with what I would expect a global company like AstraZeneca to do to meet commercial demands.

59. I saw nothing in the evidence to indicate that AstraZeneca lacked the tools and planning to be able to manage a temporary volume increase in the manufacturing of additional batches of Seroquel XR that would be associated with an AG launch. In the Seroquel XR AG business plan of July 27, 2011, it states that the inventory build for the launch would be "equivalent to 60% of 3 months of Seroquel XR volume (standard AZ Operations practice)" and would be done over the course of three months (Oct-Dec 2011). This amount is stated to be equal to 3 months of generic market volume. This is a standard amount of inventory to have on hand at launch in my experience. In the August 16, 2011 version of the same business plan, AstraZeneca lowered its projected supply needs to just "10 weeks of quetiapine fumarate AG market volume." Brian Dell further explained that this reduction was made in response to a corporate directive to lower end-of-year inventories; he wrote "I used a model similar to that used with Par for Pulmicort Respules a few years ago." This analysis suggests to me that AstraZeneca's history of successful AG launches not only provided a model for further launches, but also gave AstraZeneca confidence its ability to allocate and re-allocate capacity as necessary to support an authorized generic Seroquel XR launch.

60. In the case of Seroquel XR, AstraZeneca planned to use the exact same tablet as the brand tablet. Therefore, there was no extra cost due to set-up or cleanup of equipment required to make tablets for the AG launch.

61. Additionally, AstraZeneca had been manufacturing volumes of Seroquel XR to support its sales of over a billion dollars annually between 2012 and 2016, as well as some ROW markets for many years. Given this capacity, AstraZeneca would have been able to manufacture the AG. While AstraZeneca would have to manufacture the AG, the amount of tablets need for brand sales would decline significantly because the brand will lose significant market share upon the entry of a generic. Additionally, the total prescriptions filled with the brand and the generics do not typically exceed the brand sales prior to generic launch. As a result, other than the short period of time over which launch quantities of an AG are manufactured, no additional capacity would have been needed to manufacture an AG. The loss of generic sales to generic competitors would result in significantly less demand for the brand product, resulting in more, not less, available capacity to manufacture the generic products.

62. In addition, had Handa and AstraZeneca settled in September of 2011 for a generic launch date between May 2015 and November 2016, AstraZeneca would have had more than two years to plan for and to build product to supply Handa/Par demand as per the Supply Agreement and launch its own AG. In July 2011, AstraZeneca developed a detailed business case for the Seroquel XR AG launch that showed a "Proposed Project Start Date" of October 2011 and a "Proposed Project Completion Date" of March 26, 2012, a total project lead time of only 5 months.

63. Based on the above and my years of experience planning for authorized generic launches, it is my opinion that AstraZeneca had multiple planning, sourcing, and inventory management options to manufacture an authorized generic Seroquel XR between May 2015 and November 2016 while also continuing to manufacture sufficient quantities of the Seroquel XR tablets to sell to Handa/Par and to package for brand sales. AstraZeneca supplied the entire Seroquel XR brand market during this

> period of time and allocating its product between brand and 2 generics would be something that AstraZeneca would have been able to manage, just as it did starting in 2017.

D.I. 707-1 ¶¶ 56–63 (footnotes omitted).

Defendants argue that Ms. Marchetti's capacity opinion should be excluded under Rule 702(a). D.I. 647 at 3. Defendants say that the challenged "opinion" amounts to nothing more than a recitation of "documents and record testimony regarding AstraZeneca's manufacturing capabilities and its history with respect to launching authorized generic products, without any actual analysis by Ms. Marchetti." D.I. 647 at 9. In Defendants' view, having Ms. Marchetti recite evidence "in the guise of expert testimony solely to give an imprimatur of expert 'opinion' does not meet the Rule 702(a) standard for expert testimony," D.I. 647 at 9, which requires that the expert utilize "scientific, technical, or other specialized knowledge [that] will help the trier of fact to understand the evidence or to determine a fact in issue," Fed. R. Evid. 702(a).

I agree with Defendants and will therefore exclude Ms. Marchetti's capacity opinion because although "gathering facts in the record and regurgitating them in a fashion most favorable to Plaintiff[s] may be helpful to counsel," *Ashcraft v. Walmart, Inc.*, 2019 WL 13222756, at *7 (D. Wyo. Sept. 24, 2019), such testimony does not constitute "scientific, technical, or other specialized knowledge [that] will help the trier of fact to understand the evidence or to determine a fact in

issue" admissible under Rule 702(a). *See also In re Opana ER Antitrust Litig.*, 2021 WL 2291067, at *7 (N.D. Ill. June 4, 2021) (excluding testimony that "does not engage in any analysis or method, but instead reiterates the facts of the case and then offers his opinion based entirely on his industry experience").

Plaintiffs attempted in their briefing to refute the notion that Ms. Marchetti simply recites record evidence in her capacity opinion. D.I. 705 at 14. But at oral argument Plaintiffs conceded what is obvious from the challenged paragraphs in Ms. Marchetti's report. Counsel's words were telling: "***[E]xplaining all those documents***, I think, would be helpful and useful to the jury. Because the jury is not going to know, you know, the intricacies of a pharmaceutical company's manufacturing." 2.6.25 Tr. at 270:18–21 (docketed as D.I. 825) (emphasis added).

In short, Ms. Marchetti does not bring to bear in her capacity opinion "scientific, technical, or other specialized knowledge [that] will help the trier of fact to understand the evidence or to determine a fact in issue" and thus her opinion is inadmissible under Rule 702(a).

NOW THEREFORE, at Wilmington on this Thirty-first day of March in 2025, it is HEREBY ORDERED that Defendants' Motion to Exclude the Opinions of Susan Marchetti (*Daubert* Motion No. 4) (D.I. 646) is GRANTED IN PART

and DENIED IN PART.

CHIEF JUDGE